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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/605,826	10/29/2003	James C. Kennedy	67286-278	2825
22428	7590	06/30/2006		
FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			EXAMINER BADIO, BARBARA P	
			ART UNIT 1617	PAPER NUMBER

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/605,826	<b>Applicant(s)</b> KENNEDY ET AL.	
	<b>Examiner</b> Barbara P. Badio, Ph.D.	<b>Art Unit</b> 1617	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.  
     4a) Of the above claim(s) 2 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,6 and 11-21 is/are rejected.
- 7) ☒ Claim(s) 4 and 7-10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### **Nonfinal Office Action on the Merits**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Status of the Application***

2. Claims 1-21 are pending in the present application. Claim 2 stands withdrawn from consideration as being drawn to a nonelected invention.

### ***Double Patenting***

3. The rejections of claims 1 and 3-21 under the judicially created double patenting over claims 1-12 of US Patent 6,710,066, claims 1-12 of US Patent 5,955,490 and claims 1-2 of US Patent 5,211,938 are maintained. Applicant's statement that a terminal disclaimer will be filed upon indication of allowable subject matter is noted.

### ***Claim Objections***

4. Claims 7-10 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 7-10 have not been further treated on the merits.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 3, 6 and 11-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The court has held that an adequate written description requires a precise definition, such as by structure, formula, chemical name or physical properties, "not a mere wish or plan for obtaining the claimed chemical invention." *Eli Lilly*, 119, F.3d 1559, 1568 (Fed. Cir. 1997). The Federal Circuit has also adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications Under the 35 USC 112, 1 "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics, "including, inter alia, "functional characteristics when coupled with a known or disclosed correlation between function and structure...". *Enzo Biochem, Inc. v. Gen-Probe.*, 296 F.3d, 316, 1324-25 (Fed. Cir. 2002).

The present specification lacks an adequate description of the claimed subject matter because there is insufficient descriptive support for the phrase "a precursor of protoporphyrin IX". The present specification lacks any correlation between said functional characteristic and any structure and, thus, the skilled artisan would be unable to envision the compounds necessary for practice of the claimed invention. Thus, the claims fail to comply with the written description requirement.

7. Claims 1, 3, 6 and 11-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for 5-aminolevulinic acid, does not reasonably provide enablement for precursors of protoporphyrin IX. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are (1) the nature of the invention, (2) the breadth of the claims, (3) the state of the prior art, (4) the predictability or unpredictability of the art, (5) the amount of guidance or direction presented, (6) the presence or absence of working examples, (7) the relative skill in the art and (8) the quantity of experimentation necessary. When the above factors are taken into consideration, the examiner's position is that one skilled in the art could not perform the invention commensurate in scope with the instant claim without undue experimentation.

The instant claims recite the utilization of "a precursor of protoporphyrin IX" and, thus, encompass the utilization of all compounds, known or unknown, which might be a precursor of protoporphyrin IX. However, the present specification lacks guidance or working examples of other compounds, apart from 5-aminolevulinic acid, which are precursors of protoporphyrin IX. Therefore, in order to practice the claimed invention commensurate in scope of the instant claims, the skilled artisan in art would first have to search the prior art and test every compound, known and unknown, for its effect on the production of protoporphyrin IX. Because of the lack of guidance or working examples of other compounds which are precursors of protoporphyrin IX and, thus, that would fall within the scope of claimed invention, the experimentation necessary to practice the claimed invention is undue.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1, 3, 5, 6 and 11-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are indefinite for the following reasons:

Claim 1 recites the administration of "an effective amount of a precursor of protoporphyrin IX" but lacks structural identification of compounds encompassed by said phrase, thus, the metes and bound of the claimed invention is indefinite.

Claim 5 recites a "method of treating a non-malignant skin lesion in a human patient in which protoporphyrin IX is produced from 5-aminolevulinic acid, comprising exposing said skin lesion....". It is unclear what is being administered. Is the treatment by exposing the skin lesion to light or is it due to administration of 5-aminolevulinic acid?

Claim 6 is dependent on itself and, thus, is indefinite.

***Claim Rejections - 35 USC § 102***

10. The rejection of claims 1 and 3-21 under 35 USC 102(b) over Richter et al. (US 5,705,518) is withdrawn.

11. The rejection of claims 1, 6-16 and 18-21 under 35 USC 102(b) over Bommer et al. (US 4,977,177) is withdrawn.

12. The rejection of claims 1 and 4-21 under 35 USC 102(b) over Divaris et al. (American Journal of Pathology, 1990) is withdrawn.

***Claim Rejections - 35 USC § 103***

13. The rejection of claims 1 and 3-21 under 35 USC 103(a) over Richter et al. (US 5,705,518) in view of Bommer et al. (US 4,977,177) is withdrawn.

14. The rejection of claims 1 and 3-21 under 35 USC 103(a) over Pandey (US 5,093,349) is withdrawn.

***Allowable Subject Matter***

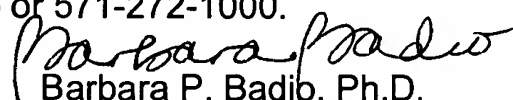
15. Claim 4 is objected to as being dependent upon a rejected base claim.

***Telephone Inquiry***

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1617